MARKED UP VERSION OF CLAIMS WITH MARKINGS TO SHOW CHANGES

1. (Original) A sterile composite graft comprising:

first and second bone blocks, each bone block defining a central through going bore having a cross section which will allow a ligament replacement to be passed there through and at least one longitudinal channel cut substantially parallel to the axis of the central through going bore in the exterior surface of said bone block and a ligament replacement mounted to said bone blocks, said ligament replacement extending through said central bore of said bone blocks and around said first and second bone blocks seated in said longitudinal channel.

2. (Original) A sterile composite graft as claimed in claim 1 wherein said ligament replacement comprises at least one tendon taken from a group of tendons consisting of a semitendinous tendon, a patellar tendon, gracilis tendon, quadriceps tendon, adductor magnus tendon, peroneus tendons, tibialis tendons and hallucis achilles tendon.

3. (Withdrawn)A sterile composite graft as claimed in claim 1 wherein said first and second bone blocks are cylindrical in shape and further include at least one suture hole drilled radially through each of said bone blocks from one of the longitudinal channels through to the central bore.

4. (Original) A sterile composite graft as claimed in claim 1 wherein said first and second bone blocks further define a rounded notch in one end leading from said central bore to a parallel longitudinal channel to accommodate said ligament replacement extending around said bone block from said central bore to a parallel longitudinal channel.

5. (Original) A sterile composite graft as claimed in claim 1 wherein said first and second bone

blocks further comprise a plurality of holes drilled radially through each of said bone blocks from an outer surface through to the central bore.

6. (Original) A sterile composite graft as claimed in claim 1 wherein said first and second bone blocks are constructed of allograft cortical bone.

7. (Original) A sterile composite graft as claimed in claim 1 wherein said first and second bone blocks are constructed of xenograft cortical bone.

8. (Original) A sterile composite graft as claimed in claim 1 wherein said first and second bone blocks are constructed of ceramic.

9. (Original) A sterile composite graft as claimed in claim 1 wherein said first and second bone blocks are constructed of bioabsorbable polymers.

10. (Withdrawn)A sterile composite graft as claimed in claim 1 wherein said first and second bone blocks define a plurality of teeth which extend outward from an outer surface of said bone block.

11. (Original) A sterile composite graft as claimed in claim 1 wherein said first and second bone blocks define a plurality of radial ribs which extend outward from an outer surface of said bone block.

12. (Original) A sterile composite graft as claimed in claim 1 wherein said first and second bone blocks have a second fixation screw channel cut in their outer surface.

13. (Withdrawn)A sterile composite graft as claimed in claim 1 wherein said first and second bone blocks are cylindrical in shape and define a plurality of holes leading from an outside surface of said bone block to said central through going bore.

14. (Original) A sterile composite graft as claimed in claim 1 wherein said first and second bone blocks are oval in shape and define a plurality of holes leading from an outside surface of said bone block to said central through going bore.

15. (Original) A sterile composite graft as claimed in claim 1 wherein said ligament replacement comprises a semitendinosus tendon.

16. (Original) A sterile composite graft as claimed in claim 1 wherein said ligament replacement comprises a patellar tendon.

17. (Original) A sterile composite graft as claimed in claim 1 wherein said ligament replacement comprises a gracilis tendon.

18. (Currently amended) A sterile composite graft as claimed in claim 1 wherein an inner face of each bone block is cut on an angle to provide a flush alignment of the bone block.

19. (Original) A sterile composite graft as claimed in claim 14 wherein the angle for a bone block to be placed in a tibial tunnel ranges from about 5 degrees to about 15 degrees.

20. (Original) A sterile composite graft as claimed in claim 14 wherein the angle for a bone block to be placed in a femoral tunnel ranges from about 15 degrees to about 30 degrees.

21. (Original) A sterile composite graft as claimed claim 14 wherein each bone block includes an additive taken from a group of additives consisting of living cells such as chondrocytes, bone marrow cells, mesenchymal stem cells, natural extracts, tissue transplants, bioadhesives, transforming growth factor (TGF-beta), insulin-like growth factor (IGF-1), platelet derived growth factor, fibroblast GF, osteopontin VEGF, blood elements.

22. (Withdrawn) A sterile bone-tendon-bone assembly comprising:

a cylindrical allograft bone block defining a central through going bore and at least two channels cut in its outer surface; a recessed pathway formed in the end of said bone block communicating with said central bore and one of said channels cut in its outer surface, a tendon replacement member comprising an allograft bone block and an integral tendon, said tendon extending through said central bore of said bone block, looped around said recessed pathway and seated in said adjacent channel longitudinally alongside said bone block and at least one suture hole cut transverse to said

central bore and intersecting said central bore in said bone block.

23. (Withdrawn) A sterile bone-tendon-bone assembly as claimed in claim 22 wherein said ligament replacement comprises a patellar tendon.

24. (Withdrawn) A sterile bone-tendon-bone assembly comprising:

first and second cylindrical allograft bone blocks, each bone block defining a central through going bore and at least two channels cut in its outer surface; a recessed pathway formed in the end of each bone block communicating with said central bore and one of said channels cut in its outer surface, a tendon replacement member extending between said first and second bone blocks through said central bore, looped around said recessed pathway and seated in said adjacent channel longitudinally alongside each of said first and second bone blocks and at least one suture hole cut transverse to said central bore and intersecting said central bore in said bone blocks.

25. (Withdrawn) A sterile bone-tendon-bone assembly as claimed in claim 24 wherein said first and second bone blocks and said at least one tendon member are asymmetrically configured with respect to each other.

26. (Withdrawn) A sterile bone-tendon-bone assembly as claimed in claim 24 wherein said first and second bone blocks has at least four flow holes having a diameter of less than about 1mm leading from the exterior surface into said central bore.

27. (Withdrawn) A sterile bone-tendon-bone assembly as claimed in claim 24 wherein said ligament replacement comprises at least one tendon taken from a group of tendons consisting of a semitendinous tendon, a patellar tendon, gracilis tendon, quadriceps tendon, adductor magnus tendon, peroneus tendons, tibialis tendons and hallucis achilles tendon.

28. (Withdrawn) A sterile bone-tendon-bone assembly comprising:

a cylindrical allograft bone block defining a central through going bore and at least two channels cut in its outer surface; a recessed pathway formed in the end of said bone block communicating with said central bore and one of said channels cut in its outer surface, a tendon replacement member comprising an allograft bone block and an integral tendon, said tendon extending through said central bore of said bone block, looped around said recessed pathway and seated in said adjacent channel longitudinally alongside said bone block and at least one suture hole cut transverse to said central bore and intersecting said central bore in said bone block.

29 (Withdrawn) A sterile bone-tendon-bone assembly as claimed in claim 28 wherein said ligament replacement comprises a patellar tendon.

30 (Withdrawn) A sterile bone-tendon-bone assembly comprising:

first and second cylindrical allograft bone blocks defining a central bore and at least one longitudinally running channel formed on the exterior surface of said bone block; a first tendon replacement strand extending between said first and second bone blocks through said central bore and longitudinally alongside each of said first and second bone blocks; and a second tendon replacement strand extending between said first and second bone blocks through said central bore and longitudinally along the sides of each of said first and second bone blocks adjacent to at least a portion of said first tendon replacement strand.

31. (Withdrawn) The sterile bone-tendon-bone assembly of claim 26 wherein said first and second bone blocks each have at least one suture hole extending radially through said bone block from said central bore through to said substantially parallel channel with a suture extending through said at least one suture hole radially cut in each of said bone blocks leading into said central bore to attach said ligament replacement strands to said first and second bone blocks.

32. (Withdrawn) The sterile bone-tendon-bone assembly of claim 30 wherein said at least one of said ligament replacement strands is xenograft tissue

33. (Withdrawn) The sterile bone-tendon-bone assembly of claim 30 wherein said at least one of said ligament replacement strands is allograft tissue

34. (Withdrawn) A sterile bone-tendon-bone assembly of claim 30 said ligament replacement comprises at least one tendon taken from a group of tendons consisting of a semitendinous tendon, a patellar tendon, gracilis tendon, quadriceps tendon, adductor magnus tendon, peroneus tendons, tibialis tendons and hallucis achilles tendon.

35. (Withdrawn) A sterile composite graft as claimed claim 30 wherein each bone block includes an additive taken from a group of additives consisting of living cells such as chondrocytes, bone marrow cells, mesenchymal stem cells, natural extracts, tissue transplants, bioadhesives, transforming growth factor (TGF-beta), insulin-like growth factor (IGF-1), platelet derived growth factor, fibroblast GF, osteopontin VEGF, blood elements.

36. (Withdrawn) A sterile reconstructed cruciate tendon assembly comprising:

first and second allograft cylindrical bone blocks; each bone block comprising a body with a central through going bore, at least two channels cut in the outer surface of said cylindrical body and a guide recess at one end leading from said central bore to one of said channels, a tendon replacement strand extending between said first and second bone blocks is inserted through said central bore and attached longitudinally alongside each of said first and second bone blocks in one of said channels to form an asymmetrical construction.

37. (Withdrawn) A sterile reconstructed tendon assembly as claimed in claim 36 wherein said first and second bone blocks each have at least one suture hole extending radially through said bone

block from said central bore through to said substantially parallel channel with a suture extending through at least one suture hole radially cut in each of said bone blocks leading into said central bore to attach said tendon replacement sections to said first and second bone blocks.

38. (Withdrawn) A sterile reconstructed tendon assembly as claimed in claim 36 wherein said bone blocks have an angled beveled end surface.

39. (Withdrawn)A sterile reconstructed tendon assembly as claimed in claim 36 wherein said ligament replacement comprises at least one tendon taken from a group of tendons consisting of a semitendinous tendon, a patellar tendon, gracilis tendon, quadriceps tendon, adductor magnus tendon, peroneus tendons, tibialis tendons and hallucis achilles tendon.

40. (Withdrawn) A sterile reconstructed tendon assembly as claimed in claim 36 wherein said bone block outer surface is provided with a plurality of teeth extending therefrom over at least a part of its outer surface.

41. (Withdrawn) A sterile composite graft as claimed in claim 36 wherein said first and second bone blocks define a plurality of radial ribs which extend outward from an outer surface of said bone block.

42. (Withdrawn) A sterile composite graft as claimed in claim 41 wherein said ribs are radial and are formed on a portion of said outer surface forming an arc.

43. (Original) A sterile reconstructed cruciate tendon assembly comprising:

first and second bone blocks with a length greater than its width and an oval cross section; each bone block comprising a body with a central through going bore, at least two channels cut in the outer surface of said cylindrical body and a guide notch formed at one end leading from said central bore to one of said channels, a tendon replacement strand extending between said first and second bone

blocks and inserted through said central bore and attached longitudinally alongside each of said first and second bone blocks in one of said channels to form an asymmetrical construction.

44. (Original) A sterile reconstructed tendon assembly as claimed in claim 43 wherein said first and second bone blocks each have at least one suture hole extending radially through said bone block from said central bore through to said substantially parallel channel with a suture extending through at least one suture hole radially cut in each of said bone blocks leading into said central bore to attach said tendon replacement sections to said first and second bone blocks.

45. (Original) A sterile composite graft as claimed claim 43 wherein each bone block includes an additive taken from a group of additives consisting of living cells such as chondrocytes, bone marrow cells, mesenchymal stem cells, natural extracts, tissue transplants, bioadhesives, transforming growth factor (TGF-beta), insulin-like growth factor (IGF-1), platelet derived growth factor, fibroblast GF, osteopontin VEGF, blood elements.

46. (Original) A sterile reconstructed tendon assembly as claimed in claim 43 wherein said ligament replacement comprises at least one tendon taken from a group of tendons consisting of a semitendinous tendon, a patellar tendon, gracilis tendon, quadriceps tendon, adductor magnus tendon, peroneus tendons, tibialis tendons and hallucis achilles tendon.

47. (Currently Amended) A sterile bone block for use in implants comprising:

an arcuate bone block body having a central through going bore and at least one substantially parallel longitudinal channel cut in an exterior surface of said bone block body ,<u>said bone block body has an oval cross section and at least one suture hole is formed radially from an exterior surface of said bone block body through to the central bore, said bone block body defining a rounded recess formed in one end to accommodate a ligament replacement, said recess extending around a bone</u>

block end leading from said central bore to at least one substantially parallel longitudinal channel cut in the exterior surface of said bone block body.

48. (Withdrawn)A sterile bone block as claimed in claim 47 wherein said bone block body is cylindrical and at least one suture hole is formed radially from an exterior surface of said bone block body in said substantially parallel longitudinal channel through to the central bore.

49. (Canceled)

50. (Canceled)

51. (Original) A sterile bone block as claimed in claim 47 wherein said bone block body has a pathway notch formed in one end to accommodate a ligament replacement, said pathway notch extending around a bone block end leading from said central bore to the substantially parallel longitudinal channel cut in the exterior surface of said bone block body.

52. (Canceledl)

53. (Original) A sterile bone block as claimed in claim 47 wherein said bone block body has a plurality of holes of a diameter less than 1 mm drilled radially through said body through to the central bore.

54. (Withdrawn)A sterile bone block as claimed in claim 47 wherein said bone block body has a plurality of teeth which extend outward from an outer surface of said bone block body.

55. (Original) A sterile bone block as claimed in claim 47 wherein said bone block body has a plurality of radial ribs which extend outward from an outer surface of said bone block body.

56. (Original) A sterile bone block as claimed in claim 47 wherein said bone block body has a bone fixation screw channel cut in its outer surface within 90 degrees of said parallel longitudinal channel.

57. (Withdrawn) A sterile bone block as claimed in claim 47 wherein said bone block body is cylindrical in shape.

58. (Canceled)

59. (Withdrawn) A sterile bone block as claimed in claim 47 wherein an inner face of an end of said bone block body is cut on a beveled angle to provide a flush alignment of the bone block upon placement in an implant site.

60. (Withdrawn) A sterile bone block as claimed in claim 59 wherein the angle for a bone block constructed for placement in a tibial tunnel ranges from about 5 degrees to about 15 degrees.

61. (Withdrawn) A sterile bone block as claimed in claim 59 wherein the angle for a bone block constructed for placement in a femoral tunnel ranges from about 15 degrees to about 30 degrees.

62. (Withdrawn) A sterile bone block for use in implants comprising:

an allograft cylindrical bone block body having a central through going bore and at least one substantially parallel longitudinal channel cut in an exterior surface of said bone block body, said bone block body defining a rounded notch formed in one end to accommodate a ligament replacement, said notch extending around an end of bone block leading from said central bore to a substantially parallel longitudinal channel cut in the exterior surface of said bone block body, said bone block body further defining a plurality of holes drilled radially through the body of said bone block from an outer surface through to the central bore.

63. (Withdrawn) A sterile composite graft as claimed claim 62 wherein each bone block includes an additive taken from a group of additives consisting of living cells such as chondrocytes, bone marrow cells, mesenchymal stem cells, natural extracts, tissue transplants, bioadhesives, transforming growth factor (TGF-beta), insulin-like growth factor (IGF-1), platelet derived growth factor,

fibroblast GF, osteopontin VEGF, blood elements.

64. (Original) A sterile bone block for use in implants comprising:

an allograft bone block body with an oval cross section having a central through going bore and at least one substantially parallel longitudinal channel cut in an exterior surface of said bone block body, said bone block body has a rounded notch formed in one end to accommodate a ligament replacement, said notch extending around a bone block end leading from said central bore to the substantially parallel longitudinal channel cut in the exterior surface of said bone block body. said bone block body further defining a plurality of holes drilled radially through the body of said bone block from an outer surface through to the central bore.

65. (Original) A sterile composite graft as claimed claim 64 wherein each bone block includes an additive taken from a group of additives consisting of living cells such as chondrocytes, bone marrow cells, mesenchymal stem cells, natural extracts, tissue transplants, bioadhesives, transforming growth factor (TGF-beta), insulin-like growth factor (IGF-1), platelet derived growth factor, fibroblast GF, osteopontin VEGF, blood elements.

66. (Withdrawn) A method for ligament reconstruction in a joint of a body comprising the steps of:

forming a bone tunnel in each of two bones of the joint;

providing first and second bone blocks, each having a central through going bore and at least one longitudinal substantially parallel channels cut into the outer surface of said each bone block;

extending at least one ligament replacement between both of the first and second bone blocks through said central bore and along the substantially parallel channel in each bone block;

attaching said at least one ligament replacement to the first and second bone blocks;

inserting the first bone block into one of the bone tunnels;

screwing an interference bone fixation screw in between a wall of said one of the bone tunnels and an exposed bone portion of the first bone block;

inserting the second bone block into a second one of the bone tunnels;

screwing an interference bone fixation screw in between a wall of said second one of the bone tunnels and an exposed bone portion of the second bone block.

67. (Withdrawn) The method of claim 66 wherein said tendon replacement comprises at least one tendon taken from a group of tendons consisting of a semitendinous tendon, a patellar tendon, gracilis tendon, quadriceps tendon, adductor magnus tendon, peroneus tendons, tibialis tendons and hallucis achilles tendon.

68. (Withdrawn) The method of claim 66 wherein said bone blocks are partially demineralized.

69. (Withdrawn) The method of claim 66 further comprising using a second channel cut in said bone block as a seat for said interference fixation screw.

70. (Withdrawn) The method of claim 66 further comprising suturing the tendon to itself through a hole cut transverse to the longitudinal axis of the bone block to form a loop.

71. (Withdrawn) The method of claim 66 including extending the tendon structure around both of the first and second bone blocks to form a loop and suturing the loop of tendon to each of the two bone blocks.

72. (Withdrawn) A method for tendon reconstruction in a joint of a body comprising the steps of:

coring out a bone tunnel in each of two bones of the joint to form cylindrical bone tunnels;

attaching a preconstructed tendon replacement assembly comprising a tendon structure with

cylindrical allograft bone blocks secured at each end in said tunnels, each said bone block being previously machined to define a central through going bore, a channel cut into its outer surface and a rounded recess on one end leading from said central bore to said outer channel allowing said tendon structure to pass through the central bore around said notch and be seated in said outer channel

inserting a first cylindrical bone block into one of the bone tunnels;

securing the first cylindrical bone block within said one of the bone tunnels;

inserting the second cylindrical bone block into a second one of the bone tunnels; and

securing the second cylindrical bone block within said second one of the bone tunnels.

73. (Withdrawn)The method of claim 72 wherein said steps of inserting comprises placing a suture in suture holes cut in said bone block and pulling said bone blocks along said tunnels to a desired position.

74. (Withdrawn)The method of claim 72 wherein said steps of securing said bone blocks comprises screwing an interference screw in between a wall of said one of the bone tunnels and the first bone block.

75. (Withdrawn) The method of claim 72 further comprising extending the tendon structure around both of the first and second bone blocks to form a loop and suturing the loop of tendon to each of the two bone blocks.

76. (Withdrawn) The method of claim 74 further comprising using a second channel cut in sai bone block as a seat and guide for said interference screw.

REMARKS

Applicant reverses the rejection of claims 1,2, 4-9, 11, 12, 14-27, 43-47, 49-53, 55, 56, 58, 64, and 65 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Application No. 10/277,838. However applicant submits herewith a Terminal Disclaimer of the '838 application together with fee as the same has been allowed and the issue fee paid.

Applicant would point out that there has been no action with regard to Claim 76 but since the same is dependent upon Claim 74 applicant has made the assumption that this claim has been withdrawn from examination by the Examiner and has treated the same accordingly.

Applicant also traverses the rejection of claims 47, 49-52, 55, 56 and 58 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,609,636 to Kohrs et al.. Claim 47 has been amended and claims 49, 50, 52 and 58 have been canceled. Kohrs et al '636 is directed towards an implant for use in spinal stabilization and is constructed with four generally linear thread segments. The thread segments are maintained and spaced apart by rigid supports. The supports and the thread segments define a hollow implant interior exposed to an exterior of the implant. The Kohrs et al '636 implant is used to fuse adjacent vertebrae together while the present invention is used to hold tendons or ligaments in place. Kohrs et al '636 could not be successfully used for a reconstruction of a tendon assembly and does not teach the use of the same or any modification of the same for use in a tendon assembly. The end surfaces of the implant together with the flat insert channels and channels with curved bottom surfaces form a sharp end surface which could sever or tear a ligament or cause wear on same. There is no showing of a recess extending around the end of the bone block leading from

the central bore to a longitudinal channel. The channels of Kohrs '636 hold the threaded and unthreaded grips of the insertion tool. Furthermore anchor segments 60 and threaded segments 401-404 anchor the implant in place in the threaded bore between vertebrae while a screw is used in the present invention to hold the same in place.

In U.S. patent law, it is well settled that for there to be anticipation under 35 U .S.C.102. "each and every element" of the claimed invention must be found either expressly or inherently described in a. single prior art reference. *Verdegaal Bros. Inc. v. Union Oil Co. of Cal.,* 814 F.2d 1565, 1571; 2 U.S.P.Q.2d (BNA) 1051, 1053 (Fed. Cir. 1986) and references cited therein. See also, *Kloster Speedsteel AB* v. *Crucible Inc.,* 793 F.2d 1565, 1571; 230 U.S.P.Q. (BNA) 81, 84 (Fed. Cir. 1986) ("absence from the reference of any claimed element negates anticipation."); *In re Schreiber,* 128 F.3d 1473, 1477; 44 U.S.P.Q.2d (BNA) 1429, 1431 (Fed.Cir. 1997). To constitute an anticipatory reference, the prior art reference must contain an enabling disclosure. *Chester v. Miller,* 906 F.2d 1574, 1576 n.2, 15 U.S.P.Q.2d (BNA) 1333, 1336 n.2 (Fed. Cir. 1990), see also *Titanium Metals Corp.* v *Banner,* 778 F.2d 775,181, 227 U.S.P.Q. 773, 778 (Fed. Cir.1985). A reference contains an enabling disclosure when a person of ordinary skill in the art could have combined the description of the invention in the reference with his knowledge of the art to have placed himself, and thus the public, in possession of the invention. *In re Donohue,* 766 F.2d 531, 533, 226 U.S.P.Q. (BNA) 619, 621 (Fed. Cir. 1985); *In re Sheppard,* 339 F.2d 238, 242, 144 U.S.P.Q. (BNA) 42, 45 (C.C.P.A. 1964). Neither of the cited references anticipate the presently claimed invention.

In cases which are similar to the present circumstances, the courts have ruled that beyond looking at the prior art to determine if it suggests doing what the inventor has done, one must consider if the prior art provides an expectation of succeeding in the endeavor. *In re Dow Chem.,*

837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988), "Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure." Id. As noted by the court in the case of *In re Clinton,* "Obviousness does not require absolute predictability, but a reasonable expectation of success is necessary." *In re Clinton,* 527 F.2d 1226, 1228, 188 U.S.P.Q. 365, 367 (C.C.P.A.1976).

As noted by the Court in the case of *In re Gordon,* the mere fact that a prior art reference could be modified to achieve the claimed invention does not make the modification obvious unless the prior art suggested the desirability of the modification. *In re Gordon,* 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir.1984); see also *In re Laskowski,* 871 F.2d 115, 117, 10 U.S.P.Q.2d 1397, 1398 (Fed. Cir. 1989), and *Ex parte Levengood,* 28 U.S.P.Q.2d 1300, 1302 (Bd. Pat. App. & Int. 1993). Applicants respectfully submit that nowhere in the art of, record is there any suggestion to arrive at the claimed structure of the present invention.

It is submitted that the cited Kohrs et al '636 reference does not anticipate, teach or obviate the present invention. Since the obviousness objection has been overcome by a terminal disclaimer it is believed that there is no pertinent prior art directed toward the present invention.

If any additional charges are required, please charge Deposit Account Number 07-1340.

It is respectfully requested that the arguments and amendments present in the present application in condition for favorable reexamination and that the application be passed to issue.

Respectfully submitted,

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